

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/786,725 Confirmation No. 2750
Applicants : KIRK D. SWENSON et al.
Filed : February 25, 2004
Title : SAFETY BLOOD COLLECTION HOLDER
Group Art Unit : 3736
Examiner : Rene T. Towa
Customer No. : 32182
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

For the reasons set forth herein, Appellants respectfully submit that the final Office Action of February 10, 2009 is based upon improper rejections of the claims and does not establish the asserted *prima facie* case of obviousness based on the cited references.

The present invention is directed to a safety needle holder assembly having a safety shield which is rotatable about the holder housing. The holder has a forward end including a needle receiving port for receiving a needle cannula therein and an annular skirt extending about the needle receiving port. The safety shield is pivotably attached to a collar wherein the collar is received between the annular skirt and the needle receiving port of the holder housing such that the safety shield is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing. The safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing without axial movement of the collar along the axis. The collar is secured to the annular skirt via an interface fit, such as with a groove/protrusion arrangement, so that the shield pivots with respect to this annular skirt.

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06/09/2009

Sharyn Beck

Signature

Sharyn Beck

Typed name of Person Signing Certificate

Rejection of claims 1-2, 5-6, and 9 under 35 U.S.C. §103(a)

The combination of Hollister ('311) with Hollister ('842) fails to teach and/or render obvious every element of claims 1-2, 5-6, and 9, resulting in a clear deficiency in establishing a *prima facie* case of obviousness in support of the rejection of claims 1-2, 5-6, and 9. Furthermore, the combination of Hollister ('311) with Hollister ('842) fails to provide any suggestion to (A) provide an annular skirt; (B) to locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing; (C) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with this annular skirt such that the shield can pivot with respect to the collar and the annular skirt; and (D) fails to meet the requirement for a reasonable expectation of success as set forth in MPEP 2143.02 as the modification suggested in the Office Action would result in a change in the respective function of Hollister ('842).

In the Office Action, the Examiner relies on Hollister ('311) as teaching a holder assembly comprising a holder housing (2) and a safety shield (20) pivotably attached to a collar (18) wherein the collar and safety shield are axially rotatable with respect to the holder housing. As discussed at column 3, lines 23-36 of Hollister ('311), the receptacle end (6) of the holder housing (2) includes a protuberance or boss (16) about which the collar (18) is fitted via an internal circumferential groove (22).

The Examiner acknowledges that Hollister ('311) fails to teach an annular skirt such that the collar can be received between the annular skirt and the needle receiving port of the holder housing.

The Examiner then relies upon the teachings of Hollister ('842) as disclosing a holder assembly having an annular skirt extending about a receiving port. The Examiner then asserts that it would have been obvious to provide the holder assembly of Hollister ('311) with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister ('842) in order to allow an annular protrusion on the collar to externally mate with a holder housing.

Appellants respectfully disagree with the Examiner's rejection for the following reasons.

As discussed briefly above, Hollister ('311) teaches that the collar (18) is mounted on the outer surface of the receptacle end (6) of the holder housing (2) via a boss/protuberance (16).

As such, in order to perform the combination suggested in the Office Action, a complete redesign of the holder housing would be required in Hollister ('311) in order to be able to locate the mounting collar between an annular skirt and a needle receiving port.

Hollister ('842) discloses at column 6, lines 62+ that the device relied upon in the rejection is a luer lock type syringe (72) comprising an internally threaded collar (76) surrounding its male luer (74). The mating of section (2b) to male luer (74), with the addition of annular collar (76), is achieved by extension (18) at the distal end of section (2b) which threadedly mates with thread (78) at the inner circumference of collar (76). As such, Hollister ('842) teaches a completely different device than that shown by Hollister ('311). One having ordinary skill in the art would not be motivated to look to the teachings of Hollister ('842), which is directed to a luer lock syringe system, when modifying a needle holder assembly such as shown by Hollister ('311). Quite simply, Hollister ('842) teaches a skirt through collar (76), but such a skirt is to be used for an entirely different purpose, namely, to lock the needle to the syringe device. Such an interlocking engagement that locks the needle to the syringe is very different than the claimed arrangement, where the shield collar is adapted to be rotatable within the annular skirt.

According to *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395, a rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions. As stated above, Hollister ('842) is directed to a luer lock syringe (72) including an internally threaded collar (76) surrounding male luer (74). The extension (18) at the distal end of section (2b) moves along these threads (78) at the inner circumference of collar (76) to mate section (2b) with collar (76). With regard to the statement in the Office Action that the threads of the annular skirt of Hollister ('842) could be modified to include a boss and groove mechanism to allow rotation of the shield/collar assembly, Appellants respectfully disagree. Radial rotation of the safety shield and collar of Hollister ('842) about an axis of the holder housing would inevitably result in axial movement of the collar along the axis as extension (18) would travel along thread (78) in an axial direction. Hollister ('842) is a luer lock syringe, which is a completely different device than the holder assembly of Hollister ('311). Accordingly, Hollister ('842) would fail to provide any suggestion to "modify" the threads to include a boss and groove mechanism to allow for rotation of a shield/collar assembly and actually teaches away from any type of radial rotation during use due to the possibility of leakage

occurring between the luer interface of male luer (74) and section (2b), thus rendering the device inoperable. Accordingly, Hollister ('842) clearly fails to teach the claimed feature of a safety shield and the collar that are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing *without axial movement of the collar along the axis*. The suggested modification of Hollister ('311) with Hollister ('842) would result in a *change in the functioning* of the luer lock system of Hollister ('842) which is contrary to the findings in *KSR International Co. v. Teleflex Inc.*, at 1395.

Furthermore, even if, *arguendo*, one *were* motivated to include the annular skirt of Hollister ('842) for the holder assembly of Hollister ('311), one would **not** be further motivated to redesign the interfitting relationship between the mounting collar and the holder housing of Hollister ('311) so that the shield can pivot with respect to the collar and the annular skirt, where the collar is axially rotatable within the skirt as set forth in the claims.

The combination of Hollister ('311) with Hollister ('842) fails to teach or render obvious the features of claims 5 and 6. Claim 5 specifically recites that an outer surface of the collar includes a protrusion and an inner surface of the annular skirt includes a groove, the groove on the annular skirt adapted to receive the protrusion on the annular collar, thereby providing an interface fit when the collar is received between the annular skirt and the needle receiving port of the holder housing. Claim 6 specifically recites that the protrusion is annular and extends around the outer surface of the collar and the groove is annular and extends around the inner surface of the annular skirt. Neither of these features are taught by the combination of Hollister ('311) with Hollister ('842). Hollister ('311) fails to teach an annular skirt, let alone a groove within this annular skirt for cooperation with a protrusion on an outer surface of the collar. Hollister ('842) shows *threads* within an annular skirt that cooperate with an extension of a needle adapter. These threads are not equivalent to an annular groove that allows for rotation of a collar *without axial movement of the collar along the axis* of a needle holder, as specifically recited in the claims. Even if one *were* motivated to include the annular skirt of Hollister ('842) for the holder assembly of Hollister ('311), such a modification would not result in the invention as claimed and, still further, neither Hollister ('311) nor Hollister ('842) provides motivation to redesign the interfitting relationship between the mounting collar and the holder housing as specifically set forth in claims 5

and 6 so that the shield can pivot with respect to the collar and the annular skirt and where the collar is axially rotatable within the skirt as set forth in the claims.

Accordingly, the Examiner has not established the asserted *prima facie* case of obviousness based on the cited references. Reconsideration and withdrawal of claims 1-2, 5-6, and 9 under 35 U.S.C. §103(a) for obviousness is hereby requested.

Rejection of Claims 3-4 and 7-8 under 35 U.S.C. §103(a)

The Examiner acknowledges that the combination of Hollister ('311) with Hollister ('819) fails to teach the claimed features of a pivot assembly wherein a hanger bar is part of the safety shield and a hook arm is part of a collar of claims 3-4; a holder assembly wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm of claim 7; and a collar having one or more slits in a rearward portion of claim 8. The Examiner relies on Kobayashi, Newby et al., Alesi et al., and/or Gyure et al. as teaching these various features. Claims 3-4 and 7-8 depend from independent claim 1 and is believed patentable for the reasons stated above. The teachings of Kobayashi, Newby et al., Alesi et al., and/or Gyure et al. do not rectify the basic deficiencies of the combination of Hollister ('311) and Hollister ('842) with respect to independent claim 1, nor does the Office Action provide any evidence to the contrary. Accordingly, reconsideration and withdrawal of claims 3-4 and 7-8 under 35 U.S.C. §103(a) for obviousness is hereby requested.

CONCLUSION

Based upon the foregoing, Appellants assert that a *prima facie* rejection based on obviousness has not been established with respect to claims 1-9. It is therefore respectfully requested that the final rejection be withdrawn and reversed.

Respectfully submitted,

THE WEBB LAW FIRM

By 

Kirk M. Miles
Registration No. 37,891
Attorney for Appellants
436 Seventh Avenue, 700 Koppers Building
Pittsburgh, PA 15219
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com